Guidance for Industry and FDA

Guidance for Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing

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U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Clinical Chemistry and Toxicology Branch
Division of Clinical Laboratory Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions regarding this draft document should be submitted by 90 days from March 22, 2000 to Docket No. 99D-5125, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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World Wide Web/CDRH home page: http://www.fda.gov/cdrh/ode/1359.pdf , or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1359 when prompted for the document shelf number.

Draft - Not for Implementation

Guidance[1] on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing

INTRODUCTION

The Food and Drug Administration (FDA) is proposing to reclassify over-the-counter (OTC) sample collection systems for drugs of abuse testing into class I. FDA is proposing that these specimen collection systems be allowed to be marketed without prior agency approval as long as they meet the following criteria: the underlying laboratory test(s) are accurate and reliable; the laboratory performing the test(s) has adequate experience and competency; and the product has adequate labeling and methods of communicating test results to consumers. Accurate labeling will enable the lay person to understand what drugs the test can identify, the time frame within which the drugs can be detected, how to properly collect the test specimen and mail it to the laboratory, how to interpret test results and how to obtain professional counseling if needed.

If the proposed rule becomes final, adequate labeling and methods of communicating test results to consumers will be a restriction required under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) even though manufacturers of these collection systems will be exempt from premarket review. This guidance presents FDA's thinking on ways to fulfill this proposed requirement. In addition, this guidance will help manufacturers currently marketing these products under CDRH's Interim Policy regarding "Parents' Access To Tests For Drugs of Abuse."

PROPOSED LABELING

All package inserts should ensure that sample collection systems are as accurate as tests used by doctors and hospitals and reliable for use in a nonprofessional setting. The information in the package insert should include the following elements:

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Clear and simple instructions should be prepared on how to collect the sample, how to prepare and mail the specimen to minimize sample mix-up, and where to send the container(s). Whenever appropriate, instructions should include drawings or diagrams to ensure correct use.

A clear identification system should ensure that specimens are not mixed up or otherwise misidentified at the laboratory. This system should be developed in a manner that assures user anonymity.

Clear identification of what drugs are detected by the test system, including all common names associated with each of the drugs, e.g., “angel dust” or “smack”.

An explanation of the degree of accuracy that can be expected with the test system should be described in lay user terms. Sources of both analytical and biological error that may cause false positive or false negative results should be clearly and simply explained. Common over-the-counter and prescription medications, as well as foods that could potentially generate erroneous results, should be identified. Manufacturers should also include information about when and for how long after ingestion drugs are likely to exist in the specimen (e.g., urine) being collected. All statements should be truthful, substantiated by material scientific facts, and balanced.

A clear statement indicating that confirmatory testing will be conducted on all samples that initially test positive should be included

Instructions on how and when the test user can obtain test results including how to contact a trained health professional if additional interpretation of test results or follow-up counseling is needed.

Delivery of test results should be in a simple format that is easily understandable to the lay user. The report of test results should include the probability of false positive and negative results and reinforce the known sources of potential errors in results.

Instructions on how to obtain professional counseling or medical assistance should be offered to any customer who received positive results and negative results.

Device labeling should include advice that the individual's or family's physician can be contacted for options for identifying and/or treating substance abuse problems. A statement that information for talking to children about drug use and abuse can be obtained from the National Clearinghouse for Drug and Alcohol Information at 1-800-729-4889 should be included.

A statement of warnings or precautions for users appropriate to the hazard presented by the product should be included. Some medicines and foods may cause false positive results. Urine specimens may be infectious. Wash hands prior to and after handling the specimens.

Information about mechanisms for dealing with or detecting sample tampering is useful to include in the labeling and, if provided, should be clearly explained. For example, techniques to detect tampering with urine specimens may include:

a) evaluation of sample temperature at the time of collection to ensure fresh urine has been provided,

b) use of coloring agents in toilets at the sites where the samples are collected in order to ensure that dilution of the sample from toilet water does not occur, and/or

c) chemical evaluation of the sample on receipt in the laboratory to ensure the pH and creatinine are consistent with urine as a specimen source.

In addition to the information contained in the package insert, all promotions, advertising, and labeling should be balanced and reflect the material scientific facts established for the analytical systems being used.

Guidelines for labeling in vitro diagnostic products for OTC use are available in a number of documents: NCCLS "Labeling of Home-Use In Vitro Test Products; Approved Guideline (NCCLS document GP14-A)" and FDA's "Write It Right" and "Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostics (lYDs): Draft Points to Consider Regarding Labeling and Premarket Submissions." The NCCLS document is available through NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087. The FDA documents are available through the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or DSMA's Facts-on-Demand at (800) 899-0381. As with all OTC labeling, instructional material for the lay user should be directed at no more than an 7th grade reading level.

References:

Backinger CL and Kingsley PA. Write it Right. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, 1993

NCCLS. Labeling of Home Use In Vitro Testing Products: Approved Guidelines. NCCLS document GPl4-A (ISBN 1056238-299-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 10897, 1996.

Food and Drug Administration. Assessing the Safety and Effectiveness of Home-use In Vitro Diagnostics (IVDs) -- Guidance Regarding Premarket Submissions. Rockville, MD: Center for Devices and Radiological Health, 1988.